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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,955	04/15/2004	Kenneth T. Heruth	1023-362US01	8230

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EXAMINER	
HOEKSTRA, JEFFREY GERBEN	
ART UNIT	**PAPER NUMBER**
3736	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,955	HERUTH ET AL.	
	Examiner	Art Unit	
	Jeffrey G. Hoekstra	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,17-42 and 48-68* is/are pending in the application.

4a) Of the above claim(s) *7,10,13,28-42 and 48-68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,17-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 10/20/2006, amended claims 1, 8, 9, 17, 19, and 20 are acknowledged. The current rejections of the claim(s) 1-6, 8, 9, 11, and 21-27 is/are *withdrawn*.

2. The examiner acknowledges applicant's remarks concerning applicant's erroneous withdrawal of claims 12, 14, and 15. Thus, claims 12, 14, and 15 are presently examined on the merits as new claims.

3. The examiner acknowledges applicant's amendments to claims 17-20 concerning their previous dependency on erroneously withdrawn claim 15 as noted above. Thus, claims 17-20 are presently examined on the merits as new claims.

4. The following new and reiterated grounds of rejection are set forth:

Election/Restrictions

5. This application contains claims 28-42 and 44-68 drawn to an invention nonelected with traverse in Paper No. 20060717. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

7. The information disclosure statement(s) (IDS) submitted on 08/07/2006 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

Specification

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

9. Claims 44-47 are objected to because of the following informalities: dependency from canceled claim 43. Appropriate correction is required.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-6, 8-9, 11-12, 14-15, and 17-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al (US 2004/0111041 A1). Ni et al discloses a method, comprising:

- monitoring a plurality of physiological parameters of a patient via a medical device (100, 200 and 300), wherein the plurality of physiological parameters includes at least one parameter indicative of patient physical activity (abstract and paragraph 0034);
- determining when the patient is attempting to sleep (abstract);
- determining values of at least one sleep quality metric (paragraphs 0006, 0007, and 0025) that is indicative of sleep quality based on at least one of the physiological parameters, a determination that the patient is attempting to sleep, on the determined activity level; and
- periodically determining an activity level of the patient based on at least one of the physiological parameters and a determination that the patient is not attempting to sleep (paragraphs 0034 and 0035).

12. For claim 2, Ni et al discloses a method wherein determining when the patient is attempting to sleep comprises receiving an indication (the sensed activity levels via sensor 103) from the patient that the patient is attempting to sleep (paragraph 0035).

13. For claims 3 and 4, Ni et al discloses a method wherein monitoring a plurality of physiological parameters comprising monitoring (a) at least one signal that indicates posture of the patient and determining when the patient is attempting to sleep comprises determining when the patient is recumbent (paragraphs 0055 and 0056) and (b) a signal from each of a plurality of orthogonally aligned accelerometers, and determining when the patient is recumbent comprises determining when the patient is recumbent based on a DC component of each of the signals (paragraphs 0055 and 0056).

14. For claims 5 and 6, Ni et al discloses a method wherein determining when the patient is attempting to sleep comprises: (a) determining when the patient is attempting to sleep based on a physical activity level of the patient (abstract) and (b) comparing the activity level to an activity level threshold and comparing an amount of time that the activity level remains substantially below the activity level threshold to a time threshold (abstract and paragraphs 0055 and 0056).

15. For claims 8 and 9, Ni et al discloses a method wherein monitoring a plurality of physiological parameters comprises monitoring posture and blood pressure (paragraphs 0034, 0055 and 0056).

16. For claim 11, Ni et al discloses a method wherein the metric indicative of sleep quality comprises sleep latency, and determining values of the sleep quality metric comprises: identifying a first time when the patient is attempting to fall asleep; identifying a second time when the patient falls asleep based on at least one of the

physiological parameters; and determining an amount of time between the first and second times (paragraphs 0055 and 0056).

17. For claim 12, Ni et al discloses a method wherein determining values of the sleep quality metric comprises: identifying when the patient is asleep based on at least one of the physiological parameters (abstract); and determining an amount of time that the patient is asleep during a period (paragraphs 0055 and 0056).

18. For claim 14, Ni et al discloses a method wherein determining values of the sleep quality metric comprises: identifying when the patient is within a sleep state based on at least one of the physiological parameters (abstract); and determining an amount of time that the patient was within the sleep state (paragraphs 0055 and 0056).

19. For claim 15, Ni et al discloses a method wherein the sleep state comprises at least one of an S3 sleep state and an S4 sleep state (paragraphs 0003 and 0004).

20. For claim 17, Ni et al discloses a method wherein determining a value of an activity metric comprises determining at least one of a mean and a median of determined activity levels (paragraphs 0070 and 0075).

21. For claim 18, Ni et al discloses a method wherein determining a value of an activity metric comprises: comparing the at least one of the mean and the median activity level to at least one threshold; and selecting the activity metric value from a plurality of predetermined possible activity metric values based on the comparison (paragraphs 0070 and 0075).

22. For claim 19, Ni et al discloses a method wherein determining a value of an activity metric comprises: comparing each of the activity levels to a threshold value; and

determining at least one of a percentage of time above the threshold and a percentage of time below the threshold (paragraphs 0055 and 0056).

23. For claim 20, Ni et al discloses a method wherein determining a value of an activity metric comprises: comparing each of the activity levels to a threshold value; and determining an average length of time that consecutively determined activity levels were above the threshold (paragraphs 0055 and 0056).

24. For claims 21-23, Ni et al discloses a method wherein (a) periodically determining an activity level comprises periodically determining a number of activity counts (Figures 7-9); (b) a medical device delivers a therapy (paragraph 0041) to the patient according to a plurality of therapy parameter sets, the method further comprising: associating each of the determined sleep quality metric values and each of the determined activity levels with a current therapy parameter set; for each of the plurality of therapy parameter sets, determining a representative value of each of the at least one sleep quality metric based on the sleep quality metric values associated with the therapy parameter set; and for each of the plurality of therapy parameter sets, determining at least one activity metric value based on the activity levels associated with the therapy parameter set as best seen in Figure 2; and (c) presenting a list of the therapy parameter sets, associated representative sleep quality metric values, and associated activity metric values (paragraphs 0053-0056).

25. For claim 25, Ni et al discloses a method wherein a medical device comprises an implantable medical device (paragraph 0029).

26. For claims 26 and 27, Ni et al the claimed methods of using an implantable medical device including an implantable neurostimulator (10) for implanting and/or utilizing a drug pump.

Response to Arguments

27. Applicant's arguments with respect to claims 1-6, 8, 9, 11, and 21-27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

28. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JH